**No. 25-1097**

**IN THE UNITED STATES COURT OF APPEALS**
**FOR THE EIGHTH CIRCUIT**

STATE OF KANSAS, et al.

Plaintiffs-Appellants,

v.

ROBERT F. KENNEDY, JR., et al.

Defendants-Appellees.

On Appeal from the United States District Court
for the Northern District of Iowa

# BRIEF FOR APPELLEES

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## SUMMARY OF THE CASE AND STATEMENT REGARDING ORAL ARGUMENT

In May 2024, the Department of Health and Human Services issued a final rule that, among other things, imposes certain minimum staffing requirements on nursing homes participating in the Medicare and Medicaid programs. The rule provides that its staffing requirements will take effect over a staggered timeline beginning in May 2026. Plaintiffs, a collection of States, nursing home trade associations, and nursing home facilities, brought suit in October 2024 and sought a preliminary injunction. The district court declined to issue a preliminary injunction, concluding that plaintiffs had not shown irreparable harm based on staffing requirements that were not set to take effect for over a year or by relying on purported harm associated with a provision of the rule that plaintiffs did not challenge on the merits.

Plaintiffs have requested oral argument. Defendants believe that the district court's order may be readily affirmed on the grounds set forth in the district court's decision and in this brief but stand ready to present argument if the Court would find it useful in its decisional process. If the Court determines that this matter should be set for oral argument, defendants have no objection to the 20 minutes of argument per side requested by plaintiffs.

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## STATEMENT OF JURISDICTION

Plaintiffs asserted jurisdiction in the district court under 28 U.S.C. § 1331. App. 323; R. Doc. 37, at 16. On January 16, 2025, the district court issued a decision denying plaintiffs' motion for a preliminary injunction. App. 456; R. Doc. 95, at 21. That day, plaintiffs filed a notice of appeal, App. 457; R. Doc. 98, at 1, and they subsequently filed an amended notice of appeal on January 22, 2025, App. 459; R. Doc. 104, at 1. This Court has appellate jurisdiction under 28 U.S.C. § 1292(a)(1).

## STATEMENT OF THE ISSUE

In May 2024, the Department of Health and Human Services (HHS), acting through the Centers for Medicare & Medicaid Services (CMS), issued a rule that, among other things, imposed certain minimum staffing requirements on nursing homes participating in the Medicare and Medicaid programs, which CMS determined were necessary for the health, safety, and wellbeing of the nursing home residents. In this appeal, plaintiffs challenge the district court's decision to deny their motion for a preliminary injunction based on lack of irreparable harm, where the only requirements plaintiffs substantively challenged on the merits are not set to take effect for over a year. The issue presented is whether the district court abused its discretion in denying plaintiffs' motion for a preliminary injunction of the challenged HHS rule.

The most apposite authorities are the following:

- *Morehouse Enters., LLC v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 78 F.4th 1011 (8th Cir. 2023);

- *Ng v. Board of Regents of the Univ. of Minn.*, 64 F.4th 992 (8th Cir. 2023); and
- *Northport Health Servs. of Ark., LLC v. HHS*, 14 F.4th 856 (8th Cir. 2021).

The most apposite statutory provisions are the following:

- 42 U.S.C. § 1395i-3; and
- 42 U.S.C. § 1396r

## STATEMENT OF THE CASE

### A. Statutory and Regulatory Background

**1.** As part of the Social Security Act, the Medicare and Medicaid programs provide health insurance coverage for persons who are elderly, have a severe disability, or have low income. *See* 42 U.S.C. §§ 1395 to 1396w-5. Medicare is operated by the federal government, and Medicaid is a joint federal-state program. Under both Medicare and Medicaid, health care services are provided by private organizations, governmental health care facilities, and health care professionals that meet the statutory and regulatory requirements for participation. Participation in both programs is voluntary. If a medical provider chooses to participate in these programs, it enters into an agreement under which it consents to be bound by the program's conditions of participation. *See, e.g.*, *id.* §§ 1395cc, 1396a(a)(78).

In the Federal Nursing Home Reform Act (FNHRA), Pub. L. No. 100-203, tit. IV, subtitle C, 101 Stat. 1330, 1330-160-1330-221 (1987), Congress substantially revised the requirements applicable to nursing homes participating in the Medicare

and Medicaid programs.[1] Among other things, Congress established over 100 requirements that nursing homes would have to meet to participate in these programs. *See generally* 42 U.S.C. §§ 1395i-3(g), 1396r(g). These include the requirement that facilities provide nursing services, rehabilitative services, medically related social services, pharmaceutical services, and other services "to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident." *Id.* §§ 1395i-3(b)(4)(A), 1396r(b)(4)(A). Congress also required that participating facilities provide "24-hour licensed nursing services which are sufficient to meet the nursing needs of [the facility's] residents" and that they "use the services of a registered professional nurse for at least 8 consecutive hours a day, 7 days a week." *Id.* § 1396r(b)(4)(C)(i); *id.* § 1395i-3(b)(4)(C)(i) (similar).

**2.** Medicare and Medicaid are administered by the Secretary of HHS (Secretary), acting through CMS. *See, e.g.*, 42 U.S.C. §§ 1395i-3, 1395hh, 1395kk, 1396a, 1396r. With respect to nursing homes specifically, Congress directed the Secretary to ensure that program requirements are "adequate to protect the health, safety, welfare, and rights of residents and to promote the effective and efficient use of public moneys." *Id.* §§ 1395i-3(f)(1), 1396r(f)(1). Congress further authorized the

[1] Nursing homes that participate in Medicare are officially known as "skilled nursing facilities," *see* 42 U.S.C. § 1395i-3(a), and those that participate in Medicaid are known as "nursing facilities," *see id.* § 1396r(a). There is no material difference between the two categories for purposes of this case, and defendants refer to both as "nursing homes" or "long-term care facilities" throughout this brief.

Secretary to impose "such other requirements relating to the health, safety, and well-being of residents . . . as the Secretary may find necessary." *Id.* § 1395i-3(d)(4)(B); *id.* § 1396r(d)(4)(B) (similar). Following the enactment of FNHRA, Congress directed that "[a]ny regulations promulgated and applied by the Secretary . . . after the date of the enactment of [FNHRA] with respect to services described in clauses (ii), (iv), and (v) of section 1819(b)(4)(A) of the Social Security Act shall include requirements for providers of such services that are at least as strict as the requirements applicable to providers of such services prior to the enactment of [FNHRA]." Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, § 4008(h)(2)(O), 104 Stat. 1388, 1388-50.

CMS has issued numerous regulations setting out requirements that nursing homes must meet to participate in the Medicare and Medicaid programs. For example, it has required participating facilities to employ a "qualified dietitian or other clinically qualified nutrition professional," 42 C.F.R. § 483.60(a)(1), a credentialed "[i]nfection preventionist," *id.* § 483.80(b), and "professionals necessary to carry out" various facility-administration requirements, *id.* § 483.70(e)(1).

### B. The 2024 Rule

**1.** The challenged rule arises out of the long-running consideration by CMS of whether to impose minimum staffing requirements for nursing homes participating in Medicare and Medicaid. *See, e.g.*, Comm. on Nursing Home Regulation, Inst. of Med., *Improving the Quality of Care in Nursing Homes* 200-01 (1986), https://perma.cc/8GG8-

GVY8 (Institute of Medicine Study) (recognizing CMS's predecessor, the Health Care Financing Administration, had authority to incorporate "minimum nursing staff requirements" for nursing homes "into its regulatory standards" if "convincing evidence becomes available"); Omnibus Budget Reconciliation Act of 1990, § 4801(e)(17)(B), 104 Stat. at 1388-218 (requiring CMS's predecessor to study "the appropriateness of establishing minimum caregiver to resident ratios and minimum supervisor to caregiver ratios for skilled nursing facilities"); *Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities*, 81 Fed. Reg. 68,688, 68,756 (Oct. 4, 2016) (recognizing CMS could reevaluate minimum nurse staffing standards "once a sufficient amount [of data] is collected and analyzed").

In 2022, CMS commissioned a research study to determine the level and type of staffing needed to ensure safe and quality care for nursing home residents. *See* Abt Assocs., *Nursing Home Staffing Study Comprehensive Report* (June 2023), https://perma.cc/2D8J-8E6B (2022 Abt Study). The study underscored that increased nursing home staffing improves resident health and safety and was associated with concrete positive impacts in these areas. *See, e.g.*, *id.* at xiii (indicating that, "as minimum required nurse staff [hours per resident per day (HPRD)] increase, there is a corresponding increase in potential quality and safety improvements, and a decrease in expected delayed and omitted care"); *id.* at xx (noting that "[b]oth qualitative and quantitative findings from the Staffing Study indicated potential quality and safety benefits associated with increased nurse staffing").

**2.** In 2023, CMS issued a notice of proposed rulemaking highlighting continuing concerns regarding the health and safety of nursing home residents illuminated by the 2022 Abt Study and other findings showing ongoing "chronic understaffing in [long-term care] facilities," and in particular "insufficient numbers of registered nurses (RNs) and nurse aides (NAs), as evidenced from, *inter alia*, a review of data collected since 2016." *Medicare and Medicaid Programs; Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting*, 88 Fed. Reg. 61,352, 61,352 (Sept. 6, 2023). In response to these concerns, CMS proposed minimum staffing standards to supplement existing nursing-services requirements. *Id.* Specifically, CMS proposed requiring that nursing homes provide a minimum of 0.55 RN staff hours and 2.45 NA staff hours per resident per day. *Id.* at 61,353. As CMS explained, the 2022 Abt Study "demonstrated that there was a statistically significant difference in safety and quality care at 0.45 HPRD for RNs and higher including 0.55 HPRD," and "a statistically significant difference in safety and quality care at 2.45 HPRD and higher for NAs." *Id.* at 61,357. Because "the 2022 [Abt] Study did not demonstrate an association between [Licensed Practical Nurse/Licensed Vocational Nurse (LPN/LVN)] HPRD, at any level, and safe and quality care," CMS chose not to propose a separate LPN/LVN staffing standard. *Id.* CMS additionally sought comments on whether a total nurse staffing standard should also be required. *Id.* at 61,370.

CMS further proposed to independently "require an RN to be on site 24 hours per day and 7 days per week to provide skilled nursing care to all residents in accordance with resident care plans." 88 Fed. Reg. at 61,353. CMS noted that this requirement had been recommended for years to help avoid preventable safety events when no RN was present, and the value of this requirement had been bolstered by the 2022 Abt Study's findings on the connection between RN staffing and the quality of care nursing home residents receive. *See id.* at 61,371-72 (citing 2022 Abt Study's findings, other literature, and comments in a prior rulemaking supporting this requirement).

Along with these staffing proposals, CMS also proposed certain revisions to its existing facility-assessment requirement, which operates to ensure that facilities "determine the necessary resources and staff that the facility requires to care for its residents, regardless of whether or not the facility is staffed at or above the new minimum staffing requirement." 88 Fed. Reg. at 61,373. And CMS proposed a new "Medicaid Institutional Payment Transparency Reporting Provision," requiring States to report on the "percent of payments claimed by the State for Medicaid-covered services delivered by nursing facilities and [intermediate care facilities for individuals with intellectual disabilities] that are spent on compensation to direct care workers and support staff." *Id.* at 61,381, 61,383. CMS noted its concern that understaffing could impact the quality and efficiency of the care provided in these circumstances and

explained that the reporting requirement was intended to "promote better understanding and transparency" in this area. *Id.* at 61,382.

**3.** On May 10, 2024, CMS issued a final rule. *See Medicare and Medicaid Programs; Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting*, 89 Fed. Reg. 40,876 (May 10, 2024). The final rule adopted the proposed 24/7 RN requirement and per-resident staffing requirements specifying that a facility "must provide, at a minimum, 3.48 total nurse staffing [HPRD] of nursing care, with 0.55 RN HPRD and 2.45 NA HPRD." *Id.* at 40,877. The rule provides for exemptions from the minimum HPRD standards and for eight hours per day of the 24/7 RN requirement on a case-by-case basis.[2] Exemption eligibility is based on: (1) workforce unavailability, as measured by the nursing home being located in an area in which the nursing workforce for the applicable nurse staffing type is a minimum of 20 percent below the national average; (2) a facility's good faith efforts to hire and retain staff; (3) documentation of a facility's financial commitment to staffing; (4) a facility's posting of a notice of its exemption status in a prominent and public location in each resident facility; and (5) a facility's providing notices of its exemption status and the degree to which it is not in compliance with the per-resident staffing requirements to

[2] A separate, statutory waiver for all RN hours over 40 hours per week is also available to qualifying facilities. *See* 42 U.S.C. §§ 1395i-3(b)(4)(C)(ii), 1396r(b)(4)(C)(ii). The final rule "does not purport to eliminate or modify the existing statutory waiver." 89 Fed. Reg. at 40,878.

its residents and to the Office of the State Long-Term Care Ombudsman. *Id.* at 40,877-78.[3]

The rule also revised the existing facility-assessment requirement, transferring this requirement to a standalone regulatory section and imposing certain additional requirements regarding what the assessment must include and how it is used by a nursing home. 89 Fed. Reg. at 40,905-06, 40,909-10. The previous framework required a facility to assess the care required by its resident population, the staff competencies needed to provide the requisite care, and the facility's resources. *See* 42 C.F.R. § 483.70(e) (2023). Among other things, the revised provision specifies that a facility's assessment of the care required by its resident population should include an assessment of its residents' behavioral health needs and include the input of the facility's staff and management. 89 Fed. Reg. at 40,905. It also directs that the assessment be used to inform staffing decisions to ensure the availability of a sufficient number of staff with appropriate competencies, to develop a plan to recruit and retain staff, and for contingency planning. *Id.* at 40,906.

[3] A facility will not be eligible for an exemption if it (1) has failed to submit certain Payroll Based Journal (PBJ) data; (2) has been designated a Special Focus Facility based on a history of quality issues; (3) has been cited for widespread insufficient staffing or a pattern of insufficient staffing with resultant actual resident harm; or (4) has been cited at the "immediate jeopardy" level of severity with respect to insufficient staffing within the 12 months preceding the survey during which non-compliance is identified. 89 Fed. Reg. at 40,878.

Finally, the rule adopted with certain revisions the proposed Medicaid-reporting provision, requiring States to report the percentage of Medicaid payments made to nursing homes and intermediate care facilities for individuals with intellectual disabilities that are spent on compensation to direct care workers and support staff. 89 Fed. Reg. at 40,914, 40,934.

Based on concerns raised during the rulemaking regarding staffing challenges and costs, CMS announced plans for a $75 million grant program and staffing campaign to expand the nursing workforce. 89 Fed. Reg. at 40,885-86. CMS also adopted a staggered implementation schedule for the new rule to "provide additional flexibility and time for facilities to implement these changes." *Id.* at 40,886, 40,888. Under the staggered timeline, the 24/7 RN requirement must be implemented by May 11, 2026, for nonrural facilities and May 10, 2027, for rural facilities, and the per-resident staffing requirements must be implemented by May 10, 2027, for nonrural facilities and May 10, 2029, for rural facilities. *Id.* at 40,876. The Medicaid-reporting requirements must be implemented by May 10, 2028. *Id.* The rule also required all facilities to implement the revised facility-assessment requirement by August 8, 2024. *Id.*

### C. Prior Proceedings

**1.** On October 8, 2024, almost five months after the final rule was issued, plaintiffs—20 States, several nursing home trade associations, and two individual

nursing homes—filed suit. App. 24-89; R. Doc. 1. Two weeks later, plaintiffs filed a motion seeking a preliminary injunction. R. Doc. 30.

**2.** Following completion of briefing and a hearing, the district court denied plaintiffs' motion on January 16, 2025. App. 456; R. Doc. 95, at 21.

The court concluded that plaintiffs had failed to establish that any provision of the rule that they substantively challenged caused them irreparable harm. App. 455-56; R. Doc. 95, at 20-21. Plaintiffs focused their substantive challenges on the rule's 24/7 RN and per-resident staffing requirements, but the court noted that these requirements do not take effect until May 2026 at the earliest. App. 447; R. Doc. 95, at 12. Although plaintiffs asserted that the requirements were causing current financial and compliance burdens, the court determined, based on its review of the declarations that plaintiffs had submitted in connection with their preliminary injunction motion, that any such burdens were too speculative, non-imminent, and unsubstantiated to constitute irreparable harm. App. 447-50; R. Doc. 95, at 12-15. The court concluded that the merits of plaintiffs' challenges to the two staffing requirements could be addressed before May 2026. App. 450; R. Doc. 95, at 15.

Because the rule's facility-assessment requirement had taken effect, the court noted that plaintiffs had already incurred any costs associated with initial compliance. App. 451; R. Doc. 95, at 16. In light of the inability to recover such costs and the prospect that costs associated with this requirement would recur based on the need to review the assessment at least annually, the court concluded that plaintiffs had "made

a more feasible showing of irreparable harm" as to this provision. *Id.* But it recognized that plaintiffs had not argued that they were likely to succeed on the merits as to this provision. App. 451-52; R. Doc. 95, at 16-17. Rejecting the notion that a plaintiff could "cherry-pick portions of a final rule, arguing likelihood of success as to some and irreparable harm as to others," the court held that plaintiffs' "failure to make any serious argument that they are likely to succeed on their challenge to the [facility-assessment] requirement" doomed their effort to obtain a preliminary injunction on this basis as well. App. 452; R. Doc. 95, at 17.

The court also concluded that plaintiffs had failed to establish irreparable harm with respect to the Medicaid-reporting requirements set to take effect in 2028 and that plaintiffs had not in any event made any arguments as to their likelihood of success in a challenge to this provision either. App. 453; R. Doc. 95, at 18.

The court consequently held that plaintiffs had failed to demonstrate that the extraordinary remedy of a preliminary injunction should be awarded, without addressing the other preliminary-injunction factors. App. 455-56; R. Doc. 95, at 20-21.

**3.** Plaintiffs subsequently moved for an injunction pending appeal in the district court, which the court denied. App. 458; R. Doc. 103, at 1. Plaintiffs sought an injunction pending appeal in this Court as well, and that motion remains pending.

## SUMMARY OF ARGUMENT

**I.** This appeal involves a CMS rule that, among other things, imposes certain minimum staffing requirements on nursing homes participating in Medicare and Medicaid to protect the safety and wellbeing of their residents. CMS provided that these requirements would take effect over a staggered timeline beginning in May 2026. Because the earliest date upon which the new staffing requirements could affect plaintiffs was over one year away, the district court determined that it could address plaintiffs' challenges to these requirements before they took effect and rejected plaintiffs' request that it enjoin those requirements pending full review.

The district court did not abuse its discretion in doing so. Its conclusion that plaintiffs had failed to show that they would suffer any irreparable harm in the absence of a preliminary injunction while the district court resolved their challenges to the staffing requirements in the ordinary course is correct and dooms this appeal.

**A.** In the district court and on appeal, plaintiffs present substantive challenges only to the rule's minimum staffing requirements set to take effect, at the earliest, in May 2026. The district court correctly determined that plaintiffs are not presently experiencing any certain and imminent harm from these provisions. Although plaintiffs assert that they are increasing hiring efforts now to comply with the future requirements, the district court analyzed the declarations that plaintiffs submitted in support of this assertion and found that plaintiffs failed to demonstrate any concrete present harm traceable to the rule's staffing requirements. Particularly where the

district court made clear it could address plaintiffs' challenges to the rule's staffing requirements before they take effect, there is no basis to conclude that a preliminary injunction is necessary here to preserve the status quo.

**B.** Plaintiffs' efforts to assert irreparable harm based on two provisions of the rule that they do not substantively challenge on the merits also fail.

Contrary to plaintiffs' suggestion, the district court did not conclude that the rule's facility-assessment requirement would irreparably harm plaintiffs. And although plaintiffs may have incurred some costs associated with the initial requirement to perform a facility assessment by August 2024, any such past costs provide no basis for standing for prospective injunctive relief, much less irreparable harm supporting a preliminary injunction. Plaintiffs also cannot claim irreparable harm based on the need to update their facility assessments, where plaintiffs fail to identify any concrete costs associated with this requirement or to trace any such costs to the revised rule rather than the preexisting requirement it replaced.

In any event, as the district court recognized, any harms associated with the facility-assessment requirement are irrelevant, because plaintiffs failed to make any serious argument that this provision was invalid in seeking a preliminary injunction. Consistent with the requirement that a preliminary injunction be narrowly tailored to the specific harms shown by a plaintiff, the district court correctly rejected plaintiffs' mix-and-match approach to establishing the requirements for a preliminary injunction.

For similar reasons, plaintiffs cannot claim irreparable harm based on the rule's Medicaid-reporting requirement. That requirement is not set to take effect until 2028, and plaintiffs make no effort to substantiate that they are presently suffering any concrete harms that can be traced to this provision. And, like the facility-assessment requirement, they present no meaningful challenge to this requirement on the merits, such that any harms could not in any case support issuance of a preliminary injunction.

**II. A.** If this Court were to conclude that plaintiffs had established irreparable harm, remand would be appropriate to allow the district court to assess the remaining preliminary-injunction factors in the first instance. Given the district court's conclusion that plaintiffs failed to demonstrate irreparable harm, the district court did not determine the likelihood of plaintiffs' success on the merits, address the balance of equities, or consider the propriety of extraordinary relief.

**B.** Plaintiffs are in any event not likely to succeed on the merits. The rule's staffing requirements fall comfortably within the agency's authority to establish "such other requirements relating to the health and safety of residents or relating to the physical facilities thereof as the Secretary may find necessary." 42 U.S.C. § 1396r(d)(4)(B); *id.* § 1395i-3(d)(4)(B) (similar). This Court has recognized that these authorities "are broadly worded to give HHS significant leeway in deciding how best to safeguard [long-term care] residents' health and safety." *Northport Health Servs. of Ark., LLC v. HHS*, 14 F.4th 856, 870 (8th Cir. 2021). And indeed, these authorities

have long been understood to permit HHS to supplement the statutory requirements imposed on nursing homes, as the agency did here.

The challenged staffing requirements also do not conflict with any statutory provision. By imposing a statutory requirement that nursing homes "use the services of a registered professional nurse for at least 8 consecutive hours a day, 7 days a week," 42 U.S.C. § 1396r(b)(4)(C)(i)(II); *id.* § 1395i-3(b)(4)(C)(i) (similar), Congress established a floor, not a ceiling, for the nursing services a facility must provide. Nor do the rule's requirements conflict with a statutory provision allowing the waiver of this statutory requirement, where the rule expressly states that it does not eliminate or modify the statutory waiver. And although plaintiffs assert a conflict between the rule's per-resident staffing requirements and the statutory requirement that a facility provide nursing services "sufficient to meet the nursing needs of its residents," *id.* § 1396r(b)(4)(C)(i)(I); *id.* § 1395i-3(b)(4)(C)(i) (similar), that requirement too provides a statutory minimum that the rule's minimum staffing requirements complement.

The challenged staffing requirements are also not arbitrary or capricious. CMS reasonably determined that these requirements were warranted based on extensive consideration of a study that CMS had commissioned, public comments, academic literature, data collected from nursing homes, and listening sessions with residents, staff, and others. Acknowledging that the change would require additional resources and time to achieve compliance, CMS adopted a staggered implementation deadline and hardship exemptions to provide additional flexibility and time for facilities

implementing these changes. The agency explained that it adopted the minimum staffing requirements based on its consideration of newly available data, among other things. CMS also reasonably considered any reliance interests and the feasibility and costs of complying with the rule: it recognized the varying minimum staffing standards that States had adopted in the absence of federal per-resident minimum requirements and took various steps in issuing the challenged rule—like adopting the staggered implementation timeline and regulatory hardship exemptions—to allow facilities time and flexibility in coming into compliance. Plaintiffs fail to show that the agency's consideration of these aspects of the problem was not reasonable.

**C.** The balance of equities also favors defendants. For the same reasons that plaintiffs fail to demonstrate any irreparable harm in the absence of an injunction, they cannot demonstrate any such harms outweigh the government's interest in effectuating the challenged rule governing participation by nursing homes in the Medicare and Medicaid programs. At a minimum, any relief must be limited to plaintiffs, where they provide no basis to conclude that the nationwide relief they seek is necessary to redress "the plaintiff[s'] particular injury." *Gill v. Whitford*, 585 U.S. 48, 73 (2018).

## ARGUMENT

### STANDARD OF REVIEW

To obtain a preliminary injunction, plaintiffs must show that they are likely to succeed on the merits, that they will suffer irreparable harm absent a preliminary

injunction, and that the balance of the equities and the public interest favor an injunction. *See Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). As this Court has emphasized, a preliminary injunction is "an extraordinary remedy never awarded as of right." *Morehouse Enters., LLC v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 78 F.4th 1011, 1016 (8th Cir. 2023) (quotation marks omitted). This Court "review[s] the district court's material factual findings for clear error, its legal conclusions de novo, and the court's equitable judgment—the ultimate decision to grant the injunction—for an abuse of discretion." *Ng v. Board of Regents of the Univ. of Minn.*, 64 F.4th 992, 997 (8th Cir. 2023) (alterations and quotation marks omitted).

## I. PLAINTIFFS FAILED TO DEMONSTRATE IRREPARABLE HARM

To establish irreparable harm, plaintiffs must show that, absent an injunction, they are likely to suffer harm that is "certain and great and of such imminence that there is a clear and present need for equitable relief." *Morehouse Enters.*, 78 F.4th at 1017 (quotation marks omitted). The absence of irreparable injury is independently sufficient to deny a preliminary injunction, particularly "when, as is the case here," this Court is "not the only court addressing" challenges to a policy. *Id.*; *see American Health Care Ass'n v. Kennedy*, No. 2:24-cv-114 (N.D. Tex. filed May 23, 2024) (addressing similar challenges brought by, *inter alia*, LeadingAge, the parent organization to many of the organizational plaintiffs in this case). The district court properly declined to grant plaintiffs a preliminary injunction in this case based on their failure to demonstrate irreparable harm.

### A. Plaintiffs Are Not Irreparably Harmed by the Rule's Minimum Staffing Requirements.

The district court correctly concluded that plaintiffs failed to demonstrate irreparable harm from the rule's staffing requirements, which, as plaintiffs do not dispute, are not set to take effect until May 2026 at the earliest. As the district correctly found, plaintiffs' declarations failed to establish any certain and imminent harm that plaintiffs were presently experiencing from these provisions. App. 447-50; R. Doc. 95, at 12-15. The court noted that only a handful of the declarations that plaintiffs submitted even referenced current hiring or other compliance efforts, and they did not in doing so identify any concrete harms that plaintiffs were incurring traceable to the challenged rule. App. 448; R. Doc. 95, at 13. And the bulk of the declarations referenced costs that plaintiffs expected to incur in the future that were either or both too speculative and non-imminent to constitute irreparable harm warranting a preliminary injunction. App. 446-50; R. Doc. 95, at 11-15. As this Court has recognized, "[t]he goal of a preliminary injunction is to preserve the status quo until the merits are determined." *Ng*, 64 F.4th at 998 (quotation marks omitted). Where the district court made clear it could address plaintiffs' challenges to the rule's staffing requirements before May 2026, App. 450; R. Doc. 95, at 15, there is no basis to conclude that plaintiffs are irreparably harmed absent an injunction of those provisions in the interim.

On appeal, plaintiffs do not dispute that the challenged staffing requirements will not come into effect for over a year at the earliest and consequently impose no present requirements on them. They instead cite (Br. 33) their vague assertions that nursing homes are "increasing hiring efforts," without any identified connection to a particular regulatory requirement or additional quantification. App. 267; R. Doc. 30-22, at 9; *see also* App. 142; R. Doc. 30-10, at 7. As the district court correctly determined, however, these declarations fail to make a showing of harm that "is certain and great and of such imminence that there is a clear and present need for equitable relief" as required to demonstrate irreparable harm. App. 443, R. Doc. 95, at 8 (quoting *Morehouse Enters.*, 78 F.4th at 1017).

Although the rule may "strongly encourage all [long-term care] facilities to begin working towards full compliance as quickly as possible," Br. 34 (emphasis omitted) (quoting 89 Fed. Reg. at 40,912), that does not change the fact that the rule expressly adopted a staggered timeline to allow nursing homes flexibility in meeting the rule's requirements. Nor does it relieve plaintiffs of their burden to demonstrate that they are in fact suffering any certain, great, and imminent harm traceable to the rule at present. *See Morehouse Enters.*, 78 F.4th at 1017. The state plaintiffs' claim that they are suffering "unique harms" as a result of the rule, Br. 36, is similarly unavailing. Plaintiffs suggest that the rule will cause States to "spend resources on increased oversight of" nursing homes' compliance with the rule, including by processing waiver requests or investigating complaints. *Id.* But there is no assertion in the brief that

they are presently incurring any such costs to oversee compliance with provisions of the rule that have not taken effect.

No more persuasive is plaintiffs' contention that they need not provide a "detailed cost breakdown" of their asserted harms. Br. 33. As this Court has recognized, a plaintiff fails to show irreparable harm where it "do[es] not try to quantify, or clearly explain, their generally alleged compliance costs" or explain how the challenge rule "will impact [its] overall business model" in a way that will result in the alleged harm. *Morehouse Enters.*, 78 F.4th at 1018. Plaintiffs fault the district court for purportedly employing a "novel irreparable harm threshold," Br. 26, but the court simply applied the established standard reflected in this Court's decision in *Morehouse Enterprises*, among others, which plaintiffs fail even to cite. Plaintiffs' failure in this case to quantify or explain how costs assertedly being incurred in October 2024 can be traced to challenged regulatory provisions set to take effect over a year and half later similarly precludes them from being able to show irreparable harm here. *See, e.g.*, App. 143; R. Doc. at 30-10, at 8; App. 267; R. Doc. 30-22, at 9.

### B. Plaintiffs Cannot Establish Irreparable Harm Based on the Rule's Facility-Assessment or Medicaid-Reporting Requirements Either.

**1.** Plaintiffs next attempt to demonstrate irreparable harm by pointing to the rule's separate revisions to the requirement that facilities conduct assessments to determine what resources and staff are necessary to care for their residents. Plaintiffs' argument on this score fails several times over.

**a.** As an initial matter, contrary to plaintiffs' suggestion, the district court did not conclude that the facility-assessment requirement would irreparably harm plaintiffs. Rather, it held that plaintiffs "have made a more feasible showing of irreparable harm" regarding this requirement. App. 451; R. Doc. 95, at 16.

In fact, as the district court recognized, because the deadline for implementation of the revised facility-assessment requirement was in August 2024, plaintiffs necessarily have already incurred any costs associated with initial compliance and indeed had done so prior to filing this suit in October 2024. Any such past costs do not indicate that plaintiffs would suffer future harm that might provide even a basis for standing for prospective injunctive relief, much less irreparable harm absent such relief. *See, e.g.*, *Hotchkiss v. Cedar Rapids Cmty. Sch. Dist.*, 115 F.4th 889, 893 (8th Cir. 2024) ("The party seeking a preliminary injunction . . . must show a likelihood of irreparable harm in the future," and "past injury alone [is] insufficient."); *Ng*, 64 F.4th at 997-98 (delay in seeking preliminary injunction can undermine showing of irreparable harm "if the harm has occurred and the parties cannot be returned to the status quo" (quotation marks omitted)). Thus, although plaintiffs continue to cite these costs in their brief in this Court, *see, e.g.*, Br. 32, any such past costs are not relevant to the question before this Court.

Plaintiffs also attempt to claim irreparable harm based on the asserted need to "continually update" their facility assessments. Br. 28 (emphasis omitted). But the rule's requirement that facilities review and update their facility assessments at least

annually is identical to the previous facility-assessment requirement. *Compare* 42 C.F.R. § 483.71, *with id.* § 483.70(e) (2023). Plaintiffs do not identify any concrete costs associated with updating their facility assessments; nor do they attempt to tie any such costs to the final rule rather than the preexisting requirement. Here too, plaintiffs' failure to substantiate and explain any compliance costs associated with this provision forecloses their effort to show irreparable harm on this basis. *See Morehouse Enters.*, 78 F.4th at 1018.

**b.** In any event, as the district court noted, any harm that plaintiffs may assert as to the facility-assessment requirement is irrelevant because they failed to develop any argument as to the validity of this provision. App. 452; R. Doc. 95, at 17. Although plaintiffs point to passing statements in their preliminary injunction brief in the district court asserting that the facility-assessment requirement is "vague" or "unreasonable," *see* R. Doc. 30-1, at 2, 4, 15-16, the district court correctly concluded that these conclusory arguments were insufficient to present a meaningful argument that plaintiffs could show likelihood of success on the merits as to this provision. *See, e.g.*, *Cox v. Mortgage Elec. Registration Sys., Inc.*, 685 F.3d 663, 674-75 (8th Cir. 2012) (finding party waived issue by failing to "provide a meaningful explanation of the argument and citation to relevant authority in their opening brief"). And, indeed, even on appeal, plaintiffs present no meaningful argument that they are likely to succeed on the merits with respect to any challenge to the facility-assessment provision; any such argument is forfeited twice over. *See, e.g.*, *Heuton v. Ford Motor Co.*,

930 F.3d 1015, 1022 (8th Cir. 2019) ("Absent exceptional circumstances, not present here, we cannot consider issues not raised in the district court." (quotation marks omitted)); *Koehler v. Brody*, 483 F.3d 590, 599 (8th Cir. 2007) (concluding issue was forfeited where appellant "failed to argue the point in his opening brief in anything more than a conclusory manner").

That failure dooms an effort to ground plaintiffs' request for a preliminary injunction on any harm associated with the facility-assessment provision. To demonstrate entitlement to the "extraordinary remedy" of a preliminary injunction, *MPAY Inc. v. Erie Custom Comput. Applications, Inc.*, 970 F.3d 1010, 1015 (8th Cir. 2020) (quotation marks omitted), a plaintiff must show each of four factors for relief, including both likelihood of success and irreparable harm in the absence of preliminary relief. *E.g.*, *Winter*, 555 U.S. at 20. Plaintiffs identify no case permitting their mix-and-match approach to satisfying the relevant factors; to the contrary, this Court has emphasized that "[a] preliminary injunction must be narrowly tailored to remedy only the specific harms shown by the plaintiffs, rather than to enjoin all possible breaches of the law." *Dakotans for Health v. Noem*, 52 F.4th 381, 392 (8th Cir. 2022) (alteration and quotation marks omitted); *see also Labrador v. Poe ex rel. Poe*, 144 S. Ct. 921, 923 (2024) (Gorsuch, J., concurring in the grant of stay) (noting that a district court's injunction had improperly "purported to bar the State from bringing into effect portions of a statute that no party has shown, and no court has held, likely offensive to federal law").

Plaintiffs get matters exactly backwards in faulting the district court for not engaging in a severability analysis, asserting that "[a]bsent a determination that CMS intended the Rule to operate without the unlawful provision and that the Rule can so operate, the Rule must be considered as a whole when considering injunctive relief." Br. 29. But they provide no support for that proposition, which flies in the face of a preliminary injunction's extraordinary nature and the need to narrowly tailor any such relief to the particular provisions for which a plaintiff has demonstrated harm. That requirement flows from a preliminary injunction's equitable nature: A court's authority to award equitable relief is generally confined to the relief "traditionally accorded by courts of equity." *Grupo Mexicano de Desarrollo, S.A. v. Alliance Bond Fund, Inc.*, 527 U.S. 308, 319 (1999). And it is a longstanding principle of equity that injunctive relief may "be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979).

In any case, "regulations—like statutes—are presumptively severable: If parts of a regulation are invalid and other parts are not, [courts] set aside only the invalid parts unless the remaining ones cannot operate by themselves or unless the agency manifests an intent for the entire package to rise or fall together." *Board of Cty. Comm'rs v. EPA*, 72 F.4th 284, 296 (D.C. Cir. 2023). That is all the truer here given the rule's express severability provision. *See* 89 Fed. Reg. at 40,913; *see also id.* at 40,908 (noting that "[a]ll of the requirements in this finalized rule are designed to both

function independently and work together to ensure that [nursing home] residents receive the quality care required for their health and safety needs," with the minimum staffing requirements and the facility-assessment requirement "work[ing] independently to achieve the separate goals of a minimum nurse staffing requirement and an assessment of the resources that are required to care for the [nursing home's] resident population"). Plaintiffs' citation (Br. 30-31 & nn.11-13) of various indications that CMS viewed the facility-assessment requirement as an "important *complement*" to the rule's minimum staffing requirements, 89 Fed. Reg. at 40,906 (emphasis added), only underscore that the relevant requirements can operate independently.

Failing to advance their claims, plaintiffs suggest (Br. 29-32) that this Court's decisions in *Missouri v. Biden*, 112 F.4th 531 (8th Cir. 2024) (per curiam), and *Missouri v. Trump*, 128 F.4th 979 (8th Cir. 2025), support their approach. But in *Missouri*, the district court concluded that a plaintiff had established likelihood of success and irreparable harm with respect to the loan-forgiveness provisions of a rule making changes to certain student-loan programs. *See Missouri*, 112 F.4th at 535; *Missouri*, 128 F.4th at 985. On appeal, a motions panel of this Court concluded that other provisions of the rule were also causing irreparable harm to the plaintiffs, and it expanded the district court's injunction to cover those provisions as well. *See Missouri*, 112 F.4th at 535-56, 538. And in the merits panel's subsequent decision further modifying the district court's preliminary injunction, the Court, after having

determined that a preliminary injunction was appropriate, concluded that the entirety of the challenged rule should be enjoined, where it concluded that the remaining provisions could not function sensibly without the enjoined loan-forgiveness provisions. *Missouri*, 128 F.4th at 998. Nothing in the Court's decisions in that case blessed plaintiffs' efforts here to ground entitlement to equitable relief on asserted irreparable harm from a provision unchallenged on the merits. Nor, as noted above, have plaintiffs here made any sort of showing as to non-severability as the Court held the plaintiffs in *Missouri* had, where it concluded that the challenged loan forgiveness provisions "undergird the entire [challenged] plan and therefore are not severable." *Id.* Nothing similar can be said of the independent aspects of CMS's challenged rule in this case.

**2.** For similar reasons, plaintiffs' effort to ground their claim of irreparable harm in the rule's Medicaid-reporting requirement fails. The district court correctly concluded that plaintiffs failed to demonstrate irreparable harm tied to reporting requirements set to take effect in 2028. *See* App. 453; R. Doc. 95, at 18. The only support plaintiffs point to (Br. 36) in the declarations they submitted for the assertion that they are presently suffering harm as a result of this requirement is an unsubstantiated statement in a declaration by a Nebraska official that the provision "will impose costs on Nebraska well before" the provision's effective date. App. 102; R. Doc. 30-4, at 3. Plaintiffs also cite (Br. 36) the fact that the rule estimated implementation costs for the States in connection with this requirement beginning the

year after the rule's effective date. *See* 89 Fed. Reg. at 40,990. But, as the rule reflects, CMS generated this figure by dividing the total amount it had estimated it would cost for States to implement this provision by the four years they had to do so. *See id.* Nothing in the rule or the agency's cost analysis suggests that facilities are presently required to begin taking steps to implement this provision. If plaintiffs are in fact already taking any such steps as a result of the rule, they are required to show that—which they have not. Here too, plaintiffs fail to demonstrate any harm that "is certain and great and of such imminence" that a preliminary injunction is warranted. *Morehouse Enters.*, 78 F.4th at 1017 (quotation marks omitted).

And in any event, the district court correctly recognized that plaintiffs made no substantive challenge to the Medicaid-reporting provision on the merits, *see* App. 453; R. Doc. 95, at 18 n.9, nor do they do so on appeal. As discussed *supra* pp. 23-27, plaintiffs consequently cannot obtain a preliminary injunction based on any harms associated with this provision.

## II. PLAINTIFFS HAVE NOT SHOWN THE OTHER REQUIREMENTS FOR EXTRAORDINARY INJUNCTIVE RELIEF ARE MET

### A. If This Court Does Not Affirm the District Court's Irreparable-Harm Holding, Remand Is Appropriate.

For the foregoing reasons, this Court should affirm the district court's denial of a preliminary injunction based on plaintiffs' failure to establish irreparable harm. But if the Court concludes plaintiffs have established irreparable harm, it should remand the case so that the district court can assess the remaining preliminary-injunction

factors in the first instance. Because this Court is "a court of appellate review, not of first view," "remand is ordinarily the appropriate course of action when it would be beneficial for the district court to consider an argument in the first instance." *MPAY*, 970 F.3d at 1021 (alteration and quotation marks omitted); *Lankford v. Sherman*, 451 F.3d 496, 513 (8th Cir. 2006) (remanding where district court had not addressed three of four preliminary-injunction factors). Here, the district court has not yet ruled on the likelihood of plaintiffs' success on the merits, nor has it balanced the equities of plaintiffs' request for extraordinary relief. *See* App. 455-56; R. Doc. 95, at 20-21. Remand would therefore be the proper course.

### B. Plaintiffs Are Unlikely to Succeed on the Merits.

In any event, even assuming plaintiffs could demonstrate irreparable harm, they cannot show that they are likely to prevail on appeal as to the two provisions they challenge on the merits. Contrary to plaintiffs' assertions on appeal, the challenged rule fits comfortably within CMS's authority and the terms of the Medicare and Medicaid statutes and is not arbitrary or capricious.

#### 1. HHS Had Authority to Issue the Challenged Staffing Requirements.

Congress has conferred on the Secretary authority to issue rules and regulations "as may be necessary to the efficient administration of the functions with which" he is charged under the Act. 42 U.S.C. § 1302(a); *see also id.* § 1395hh(a)(1); 89 Fed. Reg. at 40,996 (citing both provisions as authority for the final rule). Alongside this broad

grant of "general rule-making authority," Congress has also given the Secretary "specific rulemaking authority with respect to nursing homes." *Resident Councils of Wash. v. Leavitt*, 500 F.3d 1025, 1033 (9th Cir. 2007) (citing 42 U.S.C. §§ 1395i-3(f), 1396r(f)), and expressly charged the Secretary with the responsibility to issue regulations and establish "such other requirements relating to the health and safety of residents or relating to the physical facilities thereof as the Secretary may find necessary," 42 U.S.C. § 1396r(d)(4)(B), *cited in* 89 Fed. Reg. at 40,879, 40,996; *see also* 42 U.S.C. § 1395i-3(d)(4)(B) (similar). As this Court has recognized, CMS's "health and safety" authorities operate "capaciously" and "are broadly worded to give HHS significant leeway in deciding how best to safeguard [long-term care] residents' health and safety." *Northport Health Servs. of Ark., LLC v. HHS*, 14 F.4th 856, 870 (8th Cir. 2021). These provisions authorize CMS to impose the challenged staffing requirements it determined "are necessary for resident health, safety, and well-being." 89 Fed. Reg. at 40,890.

Plaintiffs do not meaningfully engage with the breadth of CMS's authority to issue regulations in this area but urge instead (Br. 42, 45-46) that the Secretary lacks authority to add to the staffing-related requirements imposed by statute, *see infra* pp. 32-35. CMS has, however, for years regularly exercised its statutory authority to protect resident health and safety by promulgating additional regulatory requirements pertaining to nursing home staffing, including, for example: by requiring all facilities to employ a "qualified dietitian or other clinically qualified nutrition professional," 42

C.F.R. § 483.60(a)(1), as well as "those professionals necessary to carry out" various facility-administration requirements, *id.* § 483.70(e)(1); by requiring nursing homes to employ an "[i]nfection preventionist" with specialized training in infection prevention and control, *id.* § 483.80(b); by tying the sufficiency of a facility's nurse staffing level to the results of a facility assessment delimited by regulation, *id.* §§ 483.35, 483.71; and by establishing numerous requirements relating to the qualifications of the nursing home workforce generally, beyond that which would be required by the statute alone, *see, e.g.*, *id.* § 483.80(d) (requirements regarding vaccination of nursing home staff), *id.* § 483.70(o)(2) (work experience requirement for mandatory social work staff); *cf. id.* §§ 482.12, 482.22 (regulating hospital hiring, staffing, and budgeting under analogous "health and safety" authority, 42 U.S.C. § 1395x(e)(9)); *see also* Omnibus Budget Reconciliation Act of 1990, § 4008(h)(2)(O), 104 Stat. at 1388-50 (directing that "[a]ny regulations promulgated and applied by the Secretary . . . after the date of the enactment of [FNHRA] with respect to services described in clauses (ii), (iv), and (v) of section 1819(b)(4)(A) of the Social Security Act shall include requirements for providers of such services that are *at least as strict* as the requirements applicable to providers of such services prior to the enactment of [FNHRA]" (emphasis added)).

The Supreme Court, in turn, has upheld such provisions. *See Biden v. Missouri*, 595 U.S. 87, 90, 94 (2022) (per curiam). Far from accepting plaintiffs' cribbed view of CMS's authority, the Supreme Court has explained that "the Secretary's role in administering Medicare and Medicaid goes far beyond that of a mere bookkeeper"

and encompasses the power to impose requirements that relate to the relevant facilities' "healthcare workers themselves," even when such requirements go beyond those otherwise specified by Congress. *Id.* at 94. The Supreme Court's ruling in *Missouri* also underscores the error in plaintiffs' contention that the major-questions doctrine and constitutional avoidance demonstrate their entitlement to a preliminary injunction in a challenge to an agency rule that "fits neatly within the language of the statute." *Id.* at 93; *see also, e.g.*, *Bhatti v. Federal Hous. Fin. Agency*, 15 F.4th 848, 854 (8th Cir. 2021) ("Statutory delegation is constitutional as long as Congress lays down by legislative act an intelligible principle to which the person or body authorized to exercise the delegated authority is directed to conform." (alterations and quotation marks omitted) (quoting *Gundy v. United States*, 588 U.S. 128, 135 (2019) (plurality opinion))).

**2. The Challenged Provisions Do Not Conflict with Any Provision of the Medicare or Medicaid Statutes.**

Plaintiffs also fail to identify any conflict between the rule's 24/7 RN and per-resident staffing requirements and any statutory provision.

For the 24/7 RN requirement, plaintiffs argue (Br. 49) that, by imposing a statutory requirement that a nursing home "must use the services of a registered professional nurse for at least 8 consecutive hours a day, 7 days a week," 42 U.S.C. § 1396r(b)(4)(C)(i)(II); *id.* § 1395i-3(b)(4)(C)(i) (similar), Congress has foreclosed imposing a greater requirement by regulation. But the statutory text expressly

imposes a floor of "at least" 8 consecutive hours every day, not a ceiling. *Id.* §§ 1395i-3(b)(4)(C)(i), 1396r(b)(4)(C)(i)(II). Nothing in that provision prohibits HHS from requiring additional nursing services deemed necessary to protect the health and safety of nursing home residents.

Plaintiffs also claim (Br. 49-50) that the rule conflicts with a statutory waiver provision allowing a nursing home to be exempted from the statutory requirement to provide at least eight hours of nursing service a day, but that simply misreads the final rule. The statutory waiver provides that, "[t]o the extent that clause (i) may be deemed to require that a skilled nursing facility engage the services of a registered professional nurse for more than 40 hours a week, the Secretary is authorized to waive such requirement" if certain conditions are met. 42 U.S.C. § 1395i-3(b)(4)(C)(ii); *accord id.* § 1396r(b)(4)(C)(ii). Although the rule establishes a separate regulatory exemption that a facility could receive covering eight hours per day of the 24/7 RN requirement, CMS expressly specified that facilities that met the requirements for the statutory waiver "will still have the ability to choose which process they want to pursue to achieve regulatory flexibility from the 24/7 RN requirement," 89 Fed. Reg. at 40,899, and thus can still seek the broader exemption provided by the statutory waiver. *See also id.* at 40,878 (noting that "this rule does not purport to eliminate or modify the existing statutory waiver").

Finally, plaintiffs fail to identify (Br. 45-47) any conflict between the per-resident staffing requirements and the statutory requirement that a nursing home must

provide nursing services "sufficient to meet the nursing needs of its residents." 42 U.S.C. § 1396r(b)(4)(C)(i)(I); *id.* § 1395i-3(b)(4)(C)(i) (similar). As CMS noted in promulgating the final rule, the per-resident requirement specifies a minimum staffing requirement that does not displace the statutory requirement, and indeed, the assessment that a facility performs of its particular resident population and the resources they require for purposes of complying with the statutory mandate "will often result in facilities needing to staff higher than the minimum staffing requirements." 89 Fed. Reg. at 40,908-09. Nor does anything in the statutory requirement that "sufficient" services be provided preclude CMS from imposing specific minimum staffing requirements based on its determination that they are necessary for resident health, safety, and welfare. To the contrary, various CMS regulations provide specific requirements on top of "qualitative" standards established by the Medicare and Medicaid statutes. Br. 45 (emphasis omitted). Those include, for example, specific requirements relating to the maintenance of an infection control program and the provision of dietary services, consistent with CMS's delegated authority to "fill up the details" of the statutory scheme Congress established. *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 395 (2024); *see supra* pp. 30-31 (listing examples). And even prior to the enactment of FNHRA, a 1986 study that the Supreme Court has acknowledged formed the basis for Congress's subsequent enactment of FNHRA, *see Health & Hosp. Corp. of Marion Cty. v. Talevski*, 599 U.S. 166, 181 (2023), expressly recognized that the Executive Branch had authority to set

"minimum nursing staff requirements" if warranted. Institute of Medicine Study 200-01. The challenged regulatory provisions are consistent with that longstanding understanding. Finally, given the absence of superfluity between the statutory requirement and CMS's authority to fill in the details of the regulatory scheme, there is no role in this case for the canon (*see* Br. 44-45) that the specific governs the general. *See, e.g.*, *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645-46 (2012) (noting canon avoids "the superfluity of a specific provision that is swallowed by the general one").

### 3. The Challenged Provisions Are Not Arbitrary or Capricious.

The rule also satisfies the arbitrary-and-capricious review standard, under which the Court "defer[s] to agency action so long as an agency examined the relevant data and articulated a satisfactory explanation for its action." *Adventist Health Sys./SunBelt, Inc. v. HHS*, 17 F.4th 793, 803 (8th Cir. 2021) (alterations and quotation marks omitted). Applying this "deferential" standard, a court "simply ensures that the agency has acted within a zone of reasonableness" and "may not substitute its own policy judgment for that of the agency." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). CMS satisfied this standard in setting out the basis for the challenged requirements.

**a.** In the proposed rule, CMS explained that it had collected information over a number of years identifying ongoing health and safety issues linked to understaffing

in nursing homes. 88 Fed. Reg. at 61,352. As CMS noted, studies had shown that "staffing levels are closely correlated with the quality of care that [long-term care] facility residents receive, and with improved health outcomes," with higher staffing levels "also provid[ing] staff in [long-term care] facilities the support they need to safely care for residents" and thereby helping prevent staff burnout and resulting turnover. *Id.* CMS decided to impose the specific challenged requirements that nursing homes have an RN on-site 24/7 and maintain minimum per-resident staffing levels based on consideration of the 2022 Abt Study it had commissioned, thousands of public comments, "academic and other literature, [Payroll Based Journal (PBJ)] System data, and detailed listening sessions with residents and their families, workers, health care providers, and advocacy groups." *Id.* at 61,353; 89 Fed. Reg. at 40,877; *see also* 88 Fed. Reg. at 61,359-64 (detailing review by CMS and Abt of the "systematic literature review," "qualitative analysis," "quantitative analysis," "[c]ost and [s]avings [a]nalysis," and "listening sessions" supporting the requirements of the final rule).[4]

As CMS explained, the 2022 Abt Study demonstrated that "Total Nurse Staffing [HPRD] of 3.30 or more," "RN [HPRD] of 0.45 or more," and "NA

[4] The PBJ System was implemented in 2016 and is used by CMS to track and report staffing information submitted by nursing homes that provides detailed data on the hours worked by different staff members within a facility, allowing for evaluation of staffing levels and quality of care provided. Facilities are required to provide this data on a frequent and regular basis, and the PBJ data is auditable because it is based on payroll. 89 Fed. Reg. at 40,889. Several years of data collection are now available, and this data was used by both CMS and as part of the studies that informed the minimum staffing requirements in the final rule.

[HPRD] of 2.45 or more" all "have a strong association with safety and quality care." 89 Fed. Reg. at 40,881. The 2022 Abt Study further "identified that basic care tasks, such as bathing, toileting, and mobility assistance, are often delayed when [long-term care] facilities are understaffed," which is not sufficient to meet the nursing needs of residents. 88 Fed. Reg. at 61,356. And as CMS explained, NAs are the employees who "spend the most time providing care to residents by assisting with activities of daily living (for example, feeding, bathing, and dressing)." *Id.* at 61,367. Because the 2022 Abt Study found that "LPN/LVN [HPRD], at any level, do not appear to have any consistent association with safety and quality of care," CMS did not propose a separate LPN/LVN per-resident requirement. 89 Fed. Reg. at 40,881.

CMS further explained its decision to propose the 24/7 RN requirement as well. It noted that nursing homes provide care for residents with increasingly complex and acute health conditions, care that is provided or supervised by RNs who, as a result of their training and education, have diagnostic and assessment skills that other types of nursing staff do not. 88 Fed. Reg. at 61,371-72. Given RNs' role in nursing home residents' care, the National Academies of Science, Engineering, and Medicine (NASEM) published a report in 2022 that recommended 24/7 direct-care RN coverage. *See id.* at 61,371. CMS explained that it shared NASEM's concerns that, in the absence of such a requirement, nursing home residents "are at risk for preventable safety events when there is no RN on site, particularly during evenings, nights, weekends, and holidays." *Id.* And it noted that this requirement was further

supported by other literature, comments on prior rulemaking, listening sessions, and the results of the 2022 Abt study demonstrating the importance of RNs to the quality of care patients receive. *Id.* at 61,371-72.

In the final rule, CMS further reviewed the research and data on which it grounded the proposed requirements and considered and responded to thousands of comments, documenting its rationale for finalizing these requirements with certain modifications across more than a hundred pages of the Federal Register. *See* 89 Fed. Reg. at 40,876-41,000. At the same time, it finalized a staggered implementation timeline and hardship exemptions to "provide additional flexibility and time for facilities to implement these changes." *Id.* at 40,885-86, 40,888.

**b.** Plaintiffs fail to identify any basis to overturn the agency's reasonable determinations in this regard.

**i.** Plaintiffs first assert (Br. 52-53) that the final rule is unlawful because the agency assertedly failed to recognize a change in position. But that argument cannot withstand even cursory scrutiny. Contrary to plaintiffs' suggestion that CMS had somehow previously taken the position that it could not issue the challenged rule, CMS has been publicly considering nursing home staffing rules for decades and has consistently taken the position that increased staffing yields better health and safety outcomes for residents. For example, CMS's 2015 proposed rule regarding Reform of Requirements for Long-Term Care Facilities "included a robust discussion regarding the long-standing interest in increasing the required hours of nurse staffing per day

and the various literature surrounding the issue of minimum nurse staffing standards in [long-term care] facilities." 89 Fed. Reg. at 40,879; *see also Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities*, 80 Fed. Reg. 42,201, 42,242 (July 16, 2015).

Where CMS had previously lacked the data on which to promulgate and enforce minimum staffing requirements, it relied on new data in the challenged rule—including data newly available since the 2016 implementation of the PBJ System as well as the 2022 Abt Study that was based in part on PBJ System data—that provided a basis for the requirements at issue. *See, e.g.*, 89 Fed. Reg. at 40,879-80 ("Since issuing the 2016 final rule . . . , we have collected several years of mandated PBJ System data, which was unavailable at the time, and new evidence from the literature."); *see also Conditions of Participation for Skilled Nursing and Intermediate Care Facilities*, 45 Fed. Reg. 47,368, 47,371 (July 14, 1980) (declining to implement minimum nursing-staff ratio because agency did not have enough data to know "how much staffing will be required"). Plaintiffs do not address the new availability of the PBJ System data and flatly misdescribe the conclusions of the 2022 Abt Study by suggesting that its determination that "[*t*]*ast literature* . . . has not identified a minimum staffing level to ensure safe and quality care" represents the conclusion of the study itself. *See* 2022 Abt Study 115 (emphasis added); *see also, e.g.*, *id.* (calculating various projected safety and quality effects associated with increased staffing levels). CMS also addressed certain concerns that the agency had expressed regarding minimum staffing standards

in the past, noting, for example, that "any numeric minimum staffing requirement is not a target and facilities must assess the needs of their resident population and make comprehensive staffing decisions based on those needs." 89 Fed. Reg. at 40,883.

At bottom, plaintiffs' criticisms of the basis CMS offered for the particular staffing requirements the agency adopted in the challenged rule amount to a dispute over where to draw the line for a minimum staffing rule. But an agency "is not required to identify the optimal threshold with pinpoint precision. It is only required to identify the standard and explain its relationship to the underlying regulatory concerns." *WorldCom, Inc. v. FCC*, 238 F.3d 449, 461-62 (D.C. Cir. 2001). The Secretary did so here. *See* 89 Fed. Reg. at 40,991 ("Ultimately, we chose the comprehensive 24/7 RN, 3.48 total nurse staff HPRD, 0.55 RN HPRD, and 2.45 NA HPRD requirements in this final rule to strike a balance between ensuring resident health and safety, while preserving access to care, including discharge to community-based services."); *see also id.* (explaining CMS's consideration and rejection of various alternatives). The extensive explanation the agency provided for taking an action long contemplated and consistent with decades of research more than satisfies the minimum standards of rationality required under the Administrative Procedure Act (APA). *See, e.g.*, *Adventist Health Sys.*, 17 F.4th at 803.

To the extent any further explanation for a purported change in position were needed, moreover, CMS provided one, citing data from the COVID-19 pandemic that underscored longstanding staffing concerns, including a 2020 study involving all of

Connecticut's 215 nursing facilities that found that 20 additional minutes of RN care per resident per day was associated with 22% fewer cases of COVID-19 among residents and 26% fewer resident deaths from COVID-19. 89 Fed. Reg. at 40,880. CMS reasonably determined that these findings further suggested that increased RN staff hours had a positive effect on reducing infection transmission in nursing homes. *See id.* Collectively, the agency's proffered rationale thus constitutes "good reasons" justifying any change in policy reflected in the rule. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

**ii.** Plaintiffs' argument based on reliance interests fares no better. Plaintiffs contend (Br. 53) that CMS failed to consider reliance interests that they assert nursing home facilities and States had in operating under the statutory requirement that a facility provide staffing "sufficient to meet the nursing needs of its residents," 42 U.S.C. § 1396r(b)(4)(C)(i)(I); *id.* § 1395i-3(b)(4)(C)(i) (similar). CMS made clear, however, that the rule did not displace this statutory requirement, which may require facilities to staff above the minimum regulatory requirements based on their particular needs. *See* 89 Fed. Reg. at 40,892; *see also id.* at 40,908 (noting that the per-resident staffing requirements both automatically adjust based on the size of the facility and are designed to function in conjunction with a facility's assessment of the resources needed to care for its own particular resident population). Far from ignoring the varying state minimum staffing standards that existed in conjunction with the statutory requirement, moreover, CMS recognized in the rule that variability and

concluded that the variability in existing standards "highlight[ed] the need for national minimum staffing standards." *Id.* at 40,880; *see also id.* at 40,877, 40,886, 40,904, 40,955, 40,994 (expressly considering existing state standards and addressing how the rule would affect them). Finally, the rule recognized both that facilities would need time to implement the new requirements, adopting a staggered implementation timeline as a result, and that, where the minimum standards are not feasible for a particular facility, exemptions are available. *See id.* at 40,886; 42 C.F.R. § 483.35(h). The rule thus is not the "one-size-fits-all" requirement plaintiffs suggest, Br. 53, and the rule plainly acknowledged the varying state standards and practices by individual nursing homes that had arisen in the absence of a federal minimum staffing requirement and explained the decision to adopt the final rule.

**iii.** Plaintiffs also err in asserting (Br. 57-63) that CMS failed to consider the feasibility and costs of complying with the rule. CMS thoroughly examined the likely impact of the rule's minimum staffing standards and expressly recognized potential compliance challenges. *See* 89 Fed. Reg. at 40,885. Indeed, in faulting CMS's consideration of this issue, plaintiffs cite the precise estimates CMS offered of the additional staff nursing homes would need to add to comply with the rule's requirements. *See* Br. 58 (citing 89 Fed. Reg. at 40,958, 40,977-80). CMS also noted that the number of nursing home staff had dropped following the COVID-19 pandemic but that the situation was improving. *See* 89 Fed. Reg. at 40,885; *see also* 88 Fed. Reg. at 61,356, 61,364, 61,376-77 (considering workforce staffing challenges and

reasons to think compliance with the rule's requirements was nevertheless feasible). And the agency announced its intention to provide financial incentives to support nursing-staff recruitment, training, and retention, 89 Fed. Reg. at 40,887, and adopted a delayed implementation timeline expressly designed to ease the compliance burden on facilities, *id.* at 40,887-88. Finally, if compliance is not feasible for a facility even after delayed implementation, the rule makes hardship exemptions available. *Id.* at 40,897-98. This regulatory hardship exemption operates in addition to (not in place of) the statutory waiver process, and it is meant to "provide temporary relief to facilities that are having workforce issues." *Id.* at 40,888.

Plaintiffs complain (Br. 60-61) that CMS did not permit facilities to proactively seek exemptions, but the agency reasonably explained that it had decided to consider a facility's eligibility for an exemption as part of the annual survey of the facility's compliance with CMS standards more generally, avoiding duplicative surveys and allowing the agency to know whether a facility may have any deficiencies in compliance that would render it eligible for the hardship exemption. *See* 89 Fed. Reg. at 40,877-78, 40,902-03. And although the agency observed that the hardship exemption would be available in "limited circumstances," *id.* at 40,894, it recognized that a significant number of facilities would meet the exemption's requirement that they be located in an area with nursing-staff shortages. *See id.* at 40,887-88, 40,953. Such facilities would still need to meet the exemption's other requirements—that they make good faith efforts to hire and retain staff and document their financial

commitment to doing so—but those requirements are fully within a facility's control. *See id.* at 40,877. The rule consequently incorporates an adaptive standard that allows a facility located in an area with a nursing-staff shortage that cannot comply with the rule's requirements notwithstanding its good faith efforts and financial commitments towards doing so to seek a hardship exemption during the time it is experiencing workforce issues.

Plaintiffs also assert that the rule "irrationally discounts" the role played by LPNs and LVNs in providing nursing home services. Br. 58. But the rule reflects CMS's careful consideration of the impact of different staffing types on residents. In particular, CMS considered studies that showed increased staffing of RNs and NAs had the biggest impact on health and safety outcomes for residents, and the agency reasonably chose to impose staffing requirements specific to those positions. *See* 89 Fed. Reg. at 40,881 (noting that RN and NA per-resident staff hours "have a strong association with safety and quality care" while "LPN/LVN [HPRD], at any level, do not appear to have any consistent association with safety and quality of care"); *id.* at 40,893 (concluding there is "insufficient research evidence" to support establishing a minimum standard for LPN/LVNs). At the same time, CMS "recognize[d] that LPN/LVN professionals undoubtedly provide important services to [long-term care] facility residents," *id.* at 40,881, and made clear, among other things, that LPN and LVN staffing would count towards the 3.48 hours per resident total nurse staffing requirement. *Id.* at 40,839; *see also id.* at 40,892-93 (recognizing that "LPNs, in

addition to all staff, are vitally important to resident care" and that their staffing may help facilities comply with the rule's total per-resident staffing requirements and the statutory requirement to maintain sufficient staffing). CMS's determination to impose the specific staffing requirements it chose in this regard was reasonable.

Finally, CMS considered in depth the costs associated with the rule and reasonably determined that they were warranted. *See, e.g.*, 89 Fed. Reg. at 40,878, 40,949-50, 40,970. And it took steps to address the cost concerns raised, including through the announcement of initiatives to make it easier for individuals to enter the nursing home workforce and to provide facilities time and flexibility in meeting the rule's requirements. *See, e.g.*, *id.* at 40,894. Moreover, although plaintiffs term the rule an "unfunded staffing mandate," Br. 62, additional costs associated with the rule's staffing requirements will be factored into Medicare and Medicaid reimbursement. Section 1888(e)(5)(A) of the Social Security Act requires the Secretary to establish a "market basket" that reflects the changes over time in the prices of an appropriate mix of goods and services included in covered skilled nursing facility services. 42 U.S.C. § 1395yy(e)(5)(A); *Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2025*, 89 Fed. Reg. 64,048, 64,065 (Aug. 6, 2024). The skilled nursing facility "market basket" is used to compute the broader "market basket" percentage increase that is used to update the skilled nursing facility Federal per diem rates on an annual basis, as required by section 1888(e)(4)(E)(ii)(IV)

of the Act. 89 Fed. Reg. at 64,065. Through this process, expenditures in labor costs will be incorporated into the mix of goods and services reflected in the market basket and any associated impact of this mix would be reflected in the rate increase in payments to Medicare facilities. Medicaid, by contrast, is a joint federal-state program, which "provides to state governments federal funds that the state, after establishing a federally approved plan, uses to pay for medical aid for the poor and disadvantaged." *United States v. Baylor Univ. Med. Ctr.*, 736 F.2d 1039, 1044 (5th Cir. 1984). Where the challenged requirements of the final rule impose additional costs on Medicaid-participating facilities, States are therefore likewise able to utilize the federal funding by adjusting their reimbursement schemes accordingly.

Ultimately, CMS reasonably determined that the rule achieved the appropriate balance of interests, explaining that "[o]ur goal is to protect resident health and safety and ensure that facilities are considering the unique characteristics of their resident population in developing staffing plans, while balancing operational requirements and supporting access to care." 89 Fed. Reg. at 40,883. Plaintiffs may disagree with the balance chosen by CMS in the final rule, but the APA does not permit a plaintiff or a court to "substitute its judgment for that of the agency." *Motor Vehicle Mfrs. Ass'n of the U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Because CMS "examined the relevant data and articulated a satisfactory explanation for its action," plaintiffs' arbitrary-and-capricious challenge fails. *Adventist Health Sys.*, 17 F.4th at 803 (alterations and quotation marks omitted).

### C. The Balance of Equities and Public Interest Do Not Support a Preliminary Injunction, Much Less the Nationwide Relief Plaintiffs Seek.

**1.** As an initial matter, given plaintiffs' inability to show irreparable harm, *see supra* pp. 18-28, they cannot demonstrate that the balance of equities supports a preliminary injunction either. *See Morehouse Enters.*, 78 F.4th at 1018 ("Given the lack of irreparable harm, we do not find that the balance of equities so favors the movant that justice requires the court to intervene to preserve the status quo until the merits are determined." (quotation marks omitted)).

In any event, plaintiffs' contention (Br. 64-65) that their purported irreparable harm outweighs countervailing interests fails to persuade. When the government "is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury." *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers) (quotation marks omitted). And plaintiffs cannot discount the harm to the public by asserting that the rule is unlawful. As the Supreme Court has emphasized, "a preliminary injunction does not follow as a matter of course from a plaintiff's showing of a likelihood of success on the merits." *Benisek v. Lamone*, 585 U.S. 155, 158 (2018) (per curiam).

Nor can plaintiffs discount the positive impacts that CMS determined the rule would have. Although a divided panel of this Court suggested in a stay decision that a government agency may not be able to rely on alleged harms suffered by third parties to show irreparable harm, *see Kansas v. United States*, 124 F.4th 529, 534 (8th Cir. 2024),

preventing harm to the public has been recognized as a basis for demonstrating irreparable harm to the government. *See, e.g.*, *King*, 567 U.S. at 1303 (Roberts, C.J., in chambers) (noting, in a case in which the State of Maryland sought to collect DNA from individuals arrested for violent felonies, that the measure could help remove violent offenders from the general population before they commit other crimes likely to cause serious injuries and that the fact that "Maryland may not employ a duly enacted statute to help prevent these injuries constitutes irreparable harm"). And with respect to the balance of equities more generally, this Court has of course recognized that "[t]he third and fourth factors for a preliminary injunction—harm to the opposing party and the public interest—merge when the Government is the party opposing the preliminary injunction." *Morehouse Enters.*, 78 F.4th at 1018. That balance favors the government here, where CMS had determined that the rule both reduces the risk to nursing home residents of suffering inadequate nursing care due to understaffing and would result in concrete savings to the Medicare program. *See* 89 Fed. Reg. at 40,987-88.

**2.** Even if this Court concludes that the district court erred in not issuing a preliminary injunction and declines to remand the matter for the district court to assess the propriety of injunctive relief in the first instance, any injunctive relief "must be tailored to redress the plaintiff's particular injury." *Gill v. Whitford*, 585 U.S. 48, 73 (2018). Under settled principles of equity, "injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the

plaintiffs," *Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 765 (1994) (quotation marks omitted); *see also Dakotans for Health*, 52 F.4th at 392 (recognizing preliminary injunction "must be narrowly tailored to remedy only the specific harms shown by the plaintiffs" (alteration and quotation marks omitted)). In line with these principles, the Supreme Court has "remind[ed] lower courts of [that] foundational rule" by staying a "universal injunction" that swept more broadly than necessary to prevent harm to the plaintiffs." *Poe*, 144 S. Ct. at 927 (Gorsuch, J., concurring in the grant of stay); *id.* at 921 (order of the Court); *id.* at 933 n.4 (Kavanaugh, J., concurring in the grant of stay).

Here, any relief should be limited, at most, to facilities operated by plaintiffs and the members of the plaintiff organizations. "The Court's constitutionally prescribed role is to vindicate the individual rights of the people appearing before it." *Gill*, 585 U.S. at 72. Plaintiffs' conclusory assertion that a nationwide injunction would be more "workable" and "provide certainty," Br. 66 (quotation marks omitted), provides no basis to think that plaintiffs have any interest in relief provided to non-plaintiff States or nursing homes or that they have standing to assert claims on behalf of facilities that they do not operate or represent. Nationwide relief would indeed be particularly harmful here given that it would render meaningless another district court's consideration of similar challenges to the challenged minimum staffing requirements brought by LeadingAge—the parent organization to many of the organizational plaintiffs here—among others. *See American Health Care Ass'n v. Kennedy*, No. 2:24-cv-114 (N.D. Tex. filed May 23, 2024).

## CONCLUSION

For the foregoing reasons, the district court's order denying a preliminary injunction should be affirmed.

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 12,521 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Word for Microsoft 365 in Garamond 14-point font, a proportionally spaced typeface.

Pursuant to Circuit Rule 28A(h)(2), I further certify that the brief has been scanned for viruses, and the brief is virus free.

*s/ Leif Overvold*
Leif Overvold

## CERTIFICATE OF SERVICE

I hereby certify that on April 3, 2025, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Eighth Circuit by using the appellate CM/ECF system.

*s/ Leif Overvold*
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